DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Nashville Surgical Instruments
Sarbjeet Kumar, MD
President
2005 Kumar lane
Springfield, TN 37172

JUL 27 2015

Re: K081366
Trade/Device Name: The Kumar T-ANCHORS Hernia Set
Regulation Number: 21 CFR 878.5020
Regulation Name: Nonabsorbable polyamide surgical suture
Regulatory Class: II
Product Code: GAR, GDW
Dated (Date on orig SE ltr): June 29, 2008
Received (Date on orig SE ltr): July 29, 2008

Dear Dr. Kumar,

This letter corrects our substantially equivalent letter of July 15, 2008.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be

found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

# Indications for Use

510(k) Number (if known): K081366

Device Name: The Kumar T-ANCHORS Hernia Set

Indications For Use: The Kumar T-ANCHORS Hernia Set provides a means for fixation of prosthetic material and passage of suture during repair of hernia and soft tissue.

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K081366

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

K081366

## 510(k) Summary

JUL 15 2008

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|---|---|
| Owner | Nashville Surgical Instruments |
| Address | 2005 Kumar Lane, Springfield, TN 37172 |
| Phone | 615- 382-4996 |
| Fax | 615-382-4199 |
| Contact Person | S. S. Kumar MD |
| Date of This Summary | May 12, 2008 |
| Device Name | Kumar T-Anchors Hernia Set |
| Classification Name | Implantable Staple (21 CFR 876.1500)<br>Suture Passer (21 CFR 884.1720)<br>Polyamide Suture (21 CFR 878.5020) |
| Product Code | GDW, KOG, GAR |
| Predicate Devices | 1. AutoSuture ProTack / AutoSuture Modified Endoscopic Fascia Stapler(K963999)<br>2. Ranfac Disposable Suture Grasper Needle (K032478) |
| Device Description | Kumar T-Anchors Hernia Set supplies 8 T-Anchors that carry size 0 polyamide suture. These are deployed in pairs percutaneously through a 16 ga. needle. The sutures are tied to anchor the prosthetic material to the abdominal wall in repair of hernia or the soft tissues. |
| Indication for Use | The Kumar T-Anchors Hernia Set provides a means for fixation of prosthetic material and passage of suture during repair of hernia or soft tissues. |
| Substantial Equivalence | The device is substantially equivalent to the hernia stapler / tacker used for fixation of prosthetic material in repair of hernia and to the Disposable Suture Grasper Needle for the passage of suture for the same purpose. The device uses T-Anchors that function as both, the implantable staples (or tacks) and the sutures used with the predicate devices. The devices have the same indications for use. |
| Safety and Effectiveness | Safety and Effectiveness of the device is similar to the predicate devices and is confirmed by the 510(k) "Substantial Equivalence" Decision Making Process Chart. |